



August 31, 2023

Ki Mobility LLC  
Mark Murphy  
Vice President of Operations  
5201 Woodward Drive  
Stevens Point, Wisconsin 54481

Re: K223527

Trade/Device Name: Little Wave Clik, Rogue XP, Little Wave XP, Spark  
Regulation Number: 21 CFR 890.3850  
Regulation Name: Mechanical Wheelchair  
Regulatory Class: Class I, reserved  
Product Code: IOR  
Dated: August 29, 2023  
Received: August 30, 2023

Dear Mark Murphy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Tushar Bansal -S**

for Heather Dean, PhD  
Assistant Director, Acute Injury Devices Team  
DHT5B: Division of Neuromodulation  
and Physical Medicine Devices  
OHT5: Office of Neurological  
and Physical Medicine Devices  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

## Indications for Use

510(k) Number (if known)  
K223527

Device Name

Little Wave Klik; Rogue XP; Little Wave XP; Spark;

Indications for Use (Describe)

The Ki Mobility Little Wave Klik, Rogue XP, Little Wave XP, and Spark manual wheelchairs are intended to provide mobility to pediatrics limited to a seating position.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

|                             |  |
|-----------------------------|--|
| Applicant Name              | Ki Mobility LLC  |
| Applicant Address           | 5201 Woodward Drive Stevens Point WI 54481 United States |
| Applicant Contact Telephone | (715) 303-6447   |
| Applicant Contact           | Mr. Mark Murphy  |
| Applicant Contact Email     | mmurphy@kimobility.com                                   |

## Device Name

[21 CFR 807.92\(a\)\(2\)](#)

|                     |  |
|---------------------|--|
| Device Trade Name   | Little Wave Klik;<br>Rogue XP;<br>Little Wave XP;<br>Spark |
| Common Name         | Mechanical wheelchair                                      |
| Classification Name | Wheelchair, Mechanical                                     |
| Regulation Number   | 890.3850   |
| Product Code        | IOR  |

## Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|-------------|--|--------------|
| K983639     | Zippie GS  | IOR          |

## Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Ki Mobility Little Wave Klik manual wheelchair is intended to provide mobility to pediatrics restricted to a sitting position. The Little Wave Klik manual wheelchair can be self-propelled by the occupant with access to hand-rims on the rear wheels or moved by an attendant with access to push handles. It is a rigid frame wheelchair with a standard weight capacity for all models of 165 pounds/75 kg. The Little Wave Klik wheelchair has a welded tubular high strength 1.125" aluminum frame with bend/trim configurations that vary the seat angle, knee angle, front and rear seat heights, seat depth, and caster wing offset. Frame offsets provide more room for the user's legs without increasing the frame length or reducing seat support.

The seat frame is dimpled to create a consistent indexing detent array for frame mounted components in 0.25" increments. An adjustable clamp is used to set the rear wheel center of gravity position relative to the backrest. A set of clamps and an aluminum cross tube comprise an adjustable cross strut to set the seat width. The strut position may be adjusted for optimal positioning for rigidity for any given seat depth. The front caster mount also contains a button to mate with dimples along the front tubes for vertical caster adjustment.

The Little Wave Klik has several components intended to grow with the pediatric user either with built in adjustment, or growth kits of separate parts. The Klik cross tubes and camber tubes come in growth kits with multiple accommodated chair widths. Growth of the chair is also accommodated from footplates that can handle multiple widths and are adjustable to fit footrest length.

The Little Wave Klik manual wheelchair has a folding backrest frame for ease of storage and transport. It utilizes discrete holes to adjust the backrest angle relative to the seat tube. It also utilizes an adjustable position backrest to adjust the seat depth.

The tubular aluminum frame accommodates both seat slings and removable depth adjustable aluminum seat pans that have overlapping portions that can grow in depth. The pans and slings are available for use with wheelchair seat cushions. The backrest frame accommodates either back upholstery or planar/contoured wheelchair backrests. For adjustment, the tension adjustable back

upholstery has straps that accommodate multiple seat widths. Seat pans and slings have overlapping portions that can grow in depth. The frame is also designed to accommodate aftermarket seating.

The seat cushion is a separate medical device adapted for use to the Little Wave Klik and is the primary contact surface to the occupant along with the backrest upholstery. Little Wave Klik components such as armrests and footrests will also have contact to the occupant. The chair may be used as a seat in a motor vehicle and conforms to ISO 7176-19: 2022 as well as ANSI/RESNA WC-4 Section 19: 2017 requirements. Two sets of transit tie down loops are bolted to the frame.

The Klik XP and Klik XPe order forms are order form variations of the same device to meet different market's requirements for pricing and reimbursement. All can be configured identically.

The Ki Mobility Rogue XP manual wheelchair is intended to provide mobility to pediatrics restricted to a sitting position. The Rogue XP manual wheelchair can be self-propelled by the occupant with access to hand-rims on the rear wheels or moved by an attendant with access to push handles. It is a rigid frame wheelchair with a standard weight capacity for all models of 200 pounds/91 kg.

The Rogue XP wheelchair has a welded tubular high strength 1.375" aluminum frame with bend/trim configurations that vary the seat angle, knee angle, front and rear seat heights, seat depth. Taper frames provide additional positioning of user's legs without the use of other components or accessories.

The Rogue XP frame has an index of holes along the sides for mounting the backrest. Additional hole can be provided behind the backrest to accommodate adjustable depth. An adjustable clamp is used to set the rear wheel center of gravity position relative to the backrest. The chair utilizes a welded cross strut to maximize the rigidity of the chair. The Rogue XP has a welded caster wing for stiffness with a knuckle housing. An internal pinion allows adjustment of caster angle forwards and backwards. The caster mount takes multiple fork and caster types, including a +3/4" stem option.

The Rogue XP has several components intended to grow with the pediatric user either with built in adjustment, or growth kits of separate parts. The cross tube weldment is split in the center with an insert that can grow the chair up to 3 inches in width the rigidizer bar on the backrest has a similar split with insert to grow the width of the chair. Growth of the chair is also accommodated from footplates that can handle multiple widths and are adjustable to fit footrest length.

The Rogue XP manual wheelchair has a folding backrest frame for ease of storage and transport. It utilizes discrete holes to adjust the backrest angle relative to the seat tube.

The tubular aluminum frame accommodates both seat slings and removable aluminum seat pans. The pans and slings are available for use with wheelchair seat cushions by adherence via AB tape. The backrest frame accommodates either back upholstery or planar/contoured wheelchair backrests. For adjustment, the tension adjustable back upholstery has straps that accommodate multiple seat widths. The frame is also designed to accommodate aftermarket seating.

The seat cushion is a separate medical device adapted for use to the Rogue XP and is the primary contact surface to the occupant along with the backrest upholstery. Rogue XP components such as armrests and footrests will also have contact to the occupant.

The chair may be used as a seat in a motor vehicle and conforms to ISO 7176-19: 2022 as well as ANSI/RESNA WC-4 Section 19: 2017 requirements. Two sets of transit tie down loops are bolted to the frame.

The Rogue XP, Rogue XPe and Rogue XP TTL order forms are order form variations of the same device to meet different market's requirements for pricing and reimbursement. All can be configured identically.

The Ki Mobility Little Wave XP manual wheelchair is intended to provide mobility to pediatrics restricted to a sitting position. The Little Wave XP manual wheelchair can be self-propelled by the occupant with access to hand-rims on the rear wheels or moved by an attendant with access to push handles. It is a rigid frame wheelchair with a standard weight capacity for all models of 165 pounds/75 kg. The Little Wave XP wheelchair has a welded tubular high strength 1.375" aluminum frame with bend/trim configurations that vary the seat angle, knee angle, front and rear seat heights, seat depth, and front frame taper. Taper frames provide additional positioning of user's legs without the use of other components or accessories.

The Little Wave XP frame has an index of holes along the sides for mounting the backrest. Additional holes can be provided behind the backrest to accommodate adjustable depth. An adjustable clamp is used to set the rear wheel center of gravity position relative to the backrest. The chair utilizes a welded cross-strut to maximize the rigidity of the chair. The front caster mount is a two-part system with a clamp embedded that allows adjustment of caster angle front to back. The caster mount takes multiple fork and caster types, including a +3/4" stem option.

The Little Wave XP has several components intended to grow with the pediatric user either with built in adjustment, or growth kits of separate parts. The cross-tube weldment is split in the center with an insert that can grow the chair up to 3 inches in width. The rigidizer bar on the backrest has a similar split with insert to grow the width of the chair. Growth of the chair is also accommodated from footplates that can handle multiple widths and are adjustable to fit footrest length.

The Little Wave XP manual wheelchair has a folding backrest frame for ease of storage and transport. It utilizes discrete holes to adjust the backrest angle relative to the seat tube.

The tubular aluminum frame accommodates both seat slings and removable aluminum seat pans. The pans and slings are available for use with wheelchair seat cushions by adherence via AB tape. The backrest frame accommodates either back upholstery or planar/contoured wheelchair backrests. For adjustment, the tension adjustable back upholstery has straps that accommodate multiple seat widths. The frame is also designed to accommodate aftermarket seating.

The seat cushion is a separate medical device adapted for use to the Little Wave XP and is the primary contact surface to the occupant along with the backrest upholstery. Little Wave XP components such as armrests and footrests will also have contact to the occupant.

The chair may be used as a seat in a motor vehicle and conforms to ISO 7176-19: 2022 as well as ANSI/RESNA WC-4 Section 19: 2017 requirements. Two sets of transit tie down loops are bolted to the frame.  
All available options and accessories are listed on the order form in the labeling section of this submission.

The Ki Mobility Spark manual wheelchair is intended to provide mobility to pediatrics restricted to a sitting position. The Spark manual wheelchair can be self-propelled by the occupant with access to handrims on the rear wheels or moved by an attendant with access to push handles. It is a folding frame wheelchair with a standard weight capacity for all models of 165 pounds/75 kg.

The Spark wheelchair has a welded tubular high strength aluminum frame with configurations that vary the front and rear seat heights, seat depth, rear wheel position and caster housing position. A width adjustable cross brace connects the wheelchair side frames and allows for folding of the frame for storage.

The Spark has several components intended to grow with the pediatric user with built in adjustment within a range of its initial configuration. Arm rests offer multiple options, including a pediatric t-arm with integrated side guard, standard t-arms, angle adjustable locking extendable flip up arm rests and tubular flip up arm rests. Footplates can handle multiple widths and are adjustable to fit footrest length.

The tubular aluminum frame accommodates aluminum seat pans for use with wheelchair seat cushions. The frame is designed to accommodate aftermarket seating systems.

The Spark manual wheelchair has a folding backrest frame for ease of storage and transport. It utilizes discrete holes to adjust the backrest angle relative to the seat tube and to adjust the seat depth.

Seat cushions and backrests are separate medical devices and are primary contact surfaces to the occupant. Spark components such as armrests and footrests will also have contact to the occupant.

The chair may be used as a seat in a motor vehicle and conforms to ISO 7176-19: 2022 as well as ANSI/RESNA WC-4 Section 19: 2017 requirements. Two sets of transit tie down loops are bolted to the frame.

## Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Ki Mobility Little Wave Klik, Rogue XP, Little Wave XP, and Spark manual wheelchairs are intended to provide mobility to pediatrics limited to a seating position.

## Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The Ki Mobility Little Wave Klik, Rogue XP, Little Wave XP and Spark manual wheelchairs are intended to provide mobility to persons limited to a sitting position. The primary use is by pediatrics in need of manual wheeled mobility. This is consistent with the intended use of the Zippie GS.

## Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The Ki Mobility Little Wave Klik manual wheelchair, in comparison to predicate device, shares intended use, similarity of configuration of components, wheels and accessories. The seat depth adjustment paradigms of both devices are similar, moving the backrest relative to the front frame. The Little Wave Klik utilizes an array of dimples to adjust the position of the backrest, whereas the Zippie GS utilizes discrete throughbolts. The center of gravity is adjustable on both products, with the Little Wave Klik utilizing an array of dimples, while the Zippie GS utilizes discrete through holes. The Ki Mobility Little Wave Klik uses a nonfolding welded rear frame to provide rigidity to the backrest. The Zippie GS utilizes a dual seat rail system to provide two attachment points for each back cane to provide rigidity. Footrests are separate from side frames. The Zippie GS offers both folding and nonfolding frames, while the Little Wave Klik only offers a nonfolding frame with integrated footrest tubes. Additionally, the Zippie GS offers a reversible frame, putting the large wheels at the front of the chair and the casters at the rear, while the Little Wave Klik only offers the conventional orientation with the large wheels in the rear. Different seat heights can be achieved on both products by interchanging wheels and casters, as well as by adjusting the height of the rear wheels on its support, or the casters within the caster forks. The backrest angle of both products is adjustable by use of an array of holes to set discrete seat to backrest angles. The backrests of both products fold down for stowage. The backrests of both products are either fixed height single tubes or a set of telescoping tubes to achieve the backrest heights desired. The Zippie GS provides a folding mechanism to fold the chair for stowage, while the Little Wave Klik does not fold laterally. However, the Little Wave Klik aluminum frame does not present a significant change to the safety or effectiveness of the wheelchair function and has been qualified through testing per the applicable standards. The Little Wave Klik components and accessories do not pose new risks, being as safe and effective as the predicate device. The Little Wave Klik is substantially equivalent to the predicate device in intended use, design, materials, and operating principles with no new issues of safety or effectiveness.

The Ki Mobility Rogue XP manual wheelchair, in comparison to predicate device, shares intended use, similarity of configuration of

**IOR PREDICATE COMPARISON TABLE**

| Device                | Ki Mobility Spark  | Ki Mobility Rogue XP   | Ki Mobility Little Wave XP   | Ki Mobility Little Wave CliK   | Zippie GS   |  |
|-----------------------|--|--|--|--|---|--|
| 510(k) Number         | K223527  | K223527  | K223527  | K223527  | K983639   |  |
| Intended Use          | The Ki Mobility Spark manual wheelchair is intended to provide mobility to persons limited to a sitting position.  | The Ki Mobility Rogue XP manual wheelchair is intended to provide mobility to persons limited to a sitting position.   | The Ki Mobility Little Wave XP manual wheelchair is intended to provide mobility to persons limited to a sitting position.   | The Ki Mobility Little Wave CliK manual wheelchair is intended to provide mobility to persons limited to a sitting position.   | The Zippie GS manual wheelchair is intended to provide mobility to persons limited to a sitting position.   |  |
| Indications for Use   | The Ki Mobility Spark manual wheelchair is intended to provide mobility to pediatrics limited to a seating position.   | The Ki Mobility Rogue XP manual wheelchair is intended to provide mobility to pediatrics limited to a seating position.  | The Ki Mobility Little Wave XP manual wheelchair is intended to provide mobility to pediatrics limited to a seating position.  | The Ki Mobility Little Wave CliK manual wheelchair is intended to provide mobility to pediatrics limited to a seating position.  | The Zippie GS manual wheelchair is intended to provide mobility to pediatric users limited to a sitting position.   |  |
| Design                | Ki Mobility Spark  | Ki Mobility Rogue XP   | Ki Mobility Little Wave XP   | Ki Mobility Little Wave CliK   | Zippie GS   |  |
| Weight Limit          | 165lb/75kg (with or without transit)   | 200lb/91kg (with or without transit)   | 165lb/75kg (with or without transit)   | 165lb/75kg (with or without transit)   | 165lb/75kg (with or without transit)  |  |
| Frame Material        | Aluminum   | Aluminum   | Aluminum   | Aluminum   | Aluminum  |  |
| Seat Width            | 10"-16"  | 10" – 18"  | 10" – 16"  | 8" – 16"   | 10" – 18"   |  |
| Seat Depth            | 12"-18"  | 10" – 20"  | 10" – 16"  | 8" – 16"   | 10" – 18"   |  |
| Seat Height           | (13"-21") Front Seat-to-Floor<br>(11"-18.5") Rear Seat-to-Floor  | 13.5" – 20.5" (Front Seat-to-Floor)<br>11.5 – 20" (Rear Seat-to-Floor)   | 11.5" – 20.5" (Front Seat-to-Floor)<br>11.5 – 20" (Rear Seat-to-Floor)   | 11.5" – 20.5" (Front Seat-to-Floor)<br>11.5" – 20" (Rear Seat-to-Floor)  | 14" – 20" (Front Seat-to-Floor)<br>12.5" – 20" (Rear Seat-to-Floor)   |  |
| Stowage Width         | 12.6" (Folded Laterally)   | 23.6"  | 22.6"  | 21.3"  | 11.8" (Lateral Folding Frame Option) 20.5" (Rigid Frame Option)   |  |
| Stowage Depth         | 29.5"  | 31.5"  | 28.9"  | 28.9"  | 29.5"   |  |
| Stowage Height        | 25.6"  | 24.4"  | 23.6"  | 26.6"  | 24.0"   |  |
| Transit approved?     | Yes (optional)   | Yes (optional)   | Yes (optional)   | Yes (optional)   | Yes (optional)  |  |
| Product weight        | 28.7lb   | 26lb   | 16lb   | 31lb   | 29lb  |  |
| Turning Radius        | 28.9"  | 26.4"  | 23.8"  | 20.7"  | 32.5"   |  |
| Frame Options:        | Width Adjustable Folding<br>Depth Adjustable<br>Footrest Swing Away<br>Footrest Super Low – Swing Away   | Straight frame – non-folding<br>Tapered frame – non-folding  | Straight frame – non-folding<br>Tapered frame non-folding  | Standard – non folding<br>Offset frame - non-folding   | Folding<br>Non-folding  |  |
| Back Angle Range      | 85"-115", 5" increments  | 80" - 100", 2" increments  | 81" - 102", 3" increments  | 80" - 100", 2" increments  | 85" - 120", 5" increments   |  |
| Backrest Styles       | Stroller Handle Back Post<br>Height Adjustable Straight with Push Handle<br>Dynamic Rocker Back  | Height Adjustable<br>Fixed Height<br>Fixed Height Offset   | Height Adjustable<br>Fixed Height<br>Fixed Height Offset   | Height Adjustable<br>Fixed Height<br>Fixed Height Offset   | Height adjustable<br>Fixed Height   |  |
| Back Heights          | Stroller Handle: 20"-24"<br>Height Adjustable: 13"-24"   | Adjustable height: 9"-18"<br>Fixed Height: 9"-18"<br>Fixed Height Offset: 11"-17"  | Adjustable height: 11"-18"<br>Fixed Height: 9"-18"<br>Fixed Height Offset: 11"-17"   | Height Adjustable<br>Fixed Height<br>Fixed Height Offset   | Fixed Height Stroller: 19", 22", 25"<br>Height Adj (Rigid): 16"-22" or 19"-25"<br>Height Adj (Folding): 17"-23" or 20"-26"  |  |
| Push Handles          | Std Push Handle fixed on back canes<br>Removeable Stroller Back Handle   | Low Profile Push Handle fixed on back canes<br>Folding push Handle<br>Bolt-On Push Handle<br>Ergo Stroller Handle<br>Single Stroller Handle<br>Double Stroller Handle  | Std Push Handle fixed on back canes<br>Low Profile Push Handle fixed on back canes<br>Folding push Handle<br>Bolt-On Push Handle<br>Ergo Stroller Handle<br>Single Stroller Handle<br>Double Stroller Handle   | Std Push Handle fixed on back canes<br>Low Profile Push Handle fixed on back canes<br>Folding push handle<br>Bolt-on Push Handle<br>Ergo Stroller Handle<br>Single Stroller Handle<br>Double Stroller Handle   | Fixed push handles on back canes<br>Angle adjustable push handle (non-folding only)   |  |
| Rigidizer bars        | None   | Non-adjustable Height Rigidizer Bar<br>Adjustable Height Rigidizer Bar   | Non-adjustable Height Rigidizer Bar<br>Adjustable Height Rigidizer Bar   | Adjustable Height Rigidizer Bar  | None  |  |
| Armrests              | Single Post Height Adjustable<br>Height Adjustable T-Arm (Std, Tall, Low)<br>Angle Adjustable Locking Extendable Flip Up<br>Pediatric Height Adjustable T-Arm<br>Tubular Flip up<br>Arm Pads (Std, Waterfall, Foam Grip)   | Height Adjustable T-Arm (Tall, Std, low)<br>Angle Adj. Locking Extendable Flip Up Armrest<br>Swing away armrest (short and tall)<br>Desk and Full Arm Pad – Standard and Waterfall styles<br>Foam Grip   | Height Adj. T-Arm (Std, low, tall and pediatric)<br>Tubular Flip Up Armrest<br>Locking Extendable Flip Back armrest<br>Swing away armrest<br>Desk and Full length arm pads<br>Foam grip type arm pads  | Height Adjustable T-Arm (Tall, Std, low and pediatric)<br>Tubular Flip Back Armrest<br>Angle Adj. Locking Extendable Flip Back Armrest<br>Swing away armrest (short and tall)<br>Desk and Full length arm pads<br>Foam Grip                              | Single Post (std and low)<br>T-Post w/foam pad (regular, tall)<br>Flip Up<br>Adjustable Locking Flip up<br>Length Adjustable locking flip up  |  |
| Wheel Lock            | Push to lock<br>Pull to lock<br>Push to Lock Flush Mount<br>Hemi-Wheel Locks<br><br>Extension handles (push and pull)<br>Grade Aids  | Push to Lock<br>Pull to Lock<br>Push to Lock Flush Mount<br><br>Low Profile Scissor Lock<br>Short Thro Scissor Lock<br>Under Seat Scissor Lock<br>Drum Brake<br>Dual Drum Brake w/push or pull<br>Extension handles (push and pull)<br>Grade Aids      | Push to Lock<br>Pull to lock<br><br>Low Profile Scissor lock<br>Short Thro Scissor lock<br><br>Drum brake<br>Dual Drum brake w/push or pull<br>Extension handles (push and pull)<br>Grade aids   | Push to Lock<br>Pull to lock<br>Push to lock Flush Mount<br><br>Low Profile Scissor lock<br>Short Thro Scissor lock<br><br>Drum brake<br>Dual Drum brake w/push or pull<br>Extension handles (push and pull)<br>Grade aids                               | Push to lock<br>Pull to lock<br><br>Foot Lock<br>Hub Lock (12 and 16" wheels)<br>Extension handles (push and pull)  |  |
| Anti-Tips             | Removable/swing-up rear Anti-tips  | Removable/swing-up rear Anti-tips  | Removable/swing-up rear Anti-tips  | Removable/swing-up rear Anti-tips  | Removable swing up rear anti-tips<br>Front Anti-tips  |  |
| Rear Wheels           | Stainless Steel Spoke (18Ct.): 18", 20", 22", 24"<br>Mag: 20", 22", 24"<br>Composite Fiber Spoke (18Ct.): 22" 24"  | Stainless Steel Spoke (18Ct.): 18", 20", 22", 24", 25"<br>Mag: 20", 22", 24"<br>Composite Fiber Spoke (18Ct.): 20" 22", 24", 25"<br>Composite Fiber Spoke (12Ct.): 22", 24", 25"   | Stainless Steel Spoke (18 Ct.): 18", 20", 22", 24", 24"<br>Mag: 20", 22", 24"<br>Composite Fiber Spoke (18 Ct.): 20", 22", 24"<br>Composite Fiber Spoke (12 Ct.): 22", 24"   | Stainless Steel Spoke (18 Ct.): 18", 20", 22", 24", 24"<br>Mag: 20", 22", 24"<br>Composite Fiber Spoke (18 Ct.): 20", 22", 24"<br>Composite Fiber Spoke (12 Ct.): 22", 24"   | Stainless Steel Spoke (18 Ct.): 18", 20", 22", 24", 24"<br>Mag: 20", 22", 24"<br>Composite Fiber Spoke (18 Ct.): 20", 22", 24"<br>Composite Fiber Spoke (12 Ct.): 22", 24"                | 18", 20", 22" and 24" Spoke<br>12, 16, 20", 22" and 24" mag wheels |
| Tires                 | Pneumatic<br>Pneumatic with Airless Insert<br>Pneumatic with puncture protection<br>Solid Polyurethane   | Pneumatic<br>Pneumatic with Airless Insert<br>Pneumatic with puncture protection<br>Solid Polyurethane   | Pneumatic<br>Pneumatic with Airless Insert<br>Pneumatic with Puncture Protection<br>Solid Polyurethane   | Pneumatic<br>Pneumatic with Airless Insert<br>Pneumatic with Puncture Protection<br>Solid Polyurethane   | Pneumatic<br>Pneumatic with Airless Insert<br>Solid Polyurethane  |  |
| Handrims              | Aluminum Anodized<br>Aluminum with Plastic Coating<br>Aluminum with Non-Slip Tape<br>Projection Knob with Plastic Coating<br>Ergonomic Thumb Grip: Flexible Polymer<br>Ergonomic Thumb Grip: Alum with Grip Coating  | Aluminum Anodized<br>Aluminum with Plastic Coating<br>Aluminum with Non-Slip Tape<br>Projection Knob with Plastic Coating<br>Ergonomic Thumb Grip: Flexible Polymer<br>Ergonomic Thumb Grip: Alum with Grip Coating                                    | Aluminum Anodized<br>Aluminum with Plastic Coating<br>Aluminum with Non-Slip Tape<br>Projection Knob with Plastic Coating<br>Ergonomic Thumb Grip: Flexible Polymer<br>Ergonomic Thumb Grip: Aluminum with Grip Coating                                  | Aluminum Anodized<br>Aluminum with Plastic Coating<br>Aluminum with Non-Slip Tape<br>Projection Knob with Plastic Coating<br>Ergonomic Thumb Grip: Flexible Polymer<br>Ergonomic Thumb Grip: Alum with Grip Coating                                      | Aluminum<br>Aluminum Plastic Coated<br>Projection Knob  |  |
| Camber                | 0", 2", 4"   | 0", 2", 3" (drive ready), 4", 6", 8"   | 0", 2", 3" (drive ready), 4", 6", 8"   | 0", 2", 3" (drive ready), 4", 6", 8"   | 0"  |  |
| Caster Wheels (W x Ø) | .75" Roller Blade (3", 4")<br>.75" Lighted Roller Blade (3", 4", 5")<br>1" Polyurethane (4", 5", 6", 7", 8")<br>1" Polyurethane Aluminum (4", 5")<br>1" Pneumatic (6", 8")<br>1.5" Polyurethane (4", 5", 6")<br>1.5" Soft Roll Aluminum (3", 4", 5", 6")<br>2" Polyurethane (6")<br>2" Pneumatic w/ Foam Insert (8") | 0.75" x 3", 4" - Rollerblade<br>0.75" x 3", 4", 5" - Lighted Rollerblade<br>1" x 4", 5", 6" - Polyurethane<br>1" x 4", 5" - Polyurethane Aluminum<br>1" x 6" - Pneumatic<br>1.5" x 4", 5", 6" - Polyurethane<br>1.5" x 4", 5", 6" - Soft Roll Aluminum | 0.75" x 3", 4" - Roller Blade<br>0.75" x 3", 4", 5" - Lighted Roller Blade<br>1" x 4", 5", 6" - Polyurethane<br>1" x 4", 5" - Polyurethane Aluminum<br>1" x 6" - Pneumatic<br>1.5" x 4", 5", 6" - Polyurethane<br>1.5" x 4", 5", 6" - Soft Roll Aluminum | 0.75" x 3", 4" - Roller Blade<br>0.75" x 3", 4", 5" - Lighted Roller Blade<br>1" x 4", 5", 6" - Polyurethane<br>1" x 4", 5" - Polyurethane Aluminum<br>1" x 6" - Pneumatic<br>1.5" x 4", 5", 6" - Polyurethane<br>1.5" x 4", 5", 6" - Soft Roll Aluminum | 3", 4" and 5" lighted rollerblade<br>5" low poly, 5x1.5 semi-pneumatic<br>6" poly, 6" pneu, 6x1.5 semi-pneumatic<br>8" poly, 8" pneumatic, 8x1.5 Semi-pneu.<br>8x2 pneu, 8x2 pneu/airless |  |
| Caster Forks          | Aluminum Fork<br>Fork Stem (Std, ¾" Longer, 1 ½" Longer)<br>Shock Absorbing (Aluminum, Composite)<br>Caster Pin Locks<br>Housing (Std, Performance)  | Aluminum Fork<br>Single Sided Fork<br>Shock Absorbing Fork: (Aluminum, Composite)  | Aluminum Fork<br>Single Sided Fork<br>Shock Absorbing Fork: (Aluminum, Composite)  | Aluminum Fork<br>Single Sided Fork<br>Shock Absorbing Fork: (Aluminum, Composite)  | Aluminum Fork   |  |
| Footrest Hangers      | Swing Away, Footrest, Extension Mount<br>Swing Away, Footrest, Front Mount<br>Elevating Leg Rest (PRO, PRO Pediatric)<br>Residual Limb Support<br>Hanger Release (Classic, 4 Way In)   | Integral to frame  | Integral to frame  | Integral to frame  | Swing Away Footrest, Extension mount<br>Swing Away Footrest, Front Mount<br>Elevating Footrest (ext and front mount)<br>Articulating Footrest (ext. mount)                                |  |
| Footplates            | Composite<br>Composite Angle Adjustable<br>Aluminum Angle Adjustable<br>Aluminum Locking Multi-Angle Adjustable<br>One Piece Flip Up Adjustable  | Tubular w/o Footplate (Open)<br>Tubular with Plastic Footplate<br>Aluminum Angle Adj.<br>Aluminum Angle Adj. with Riser<br>High Mount Aluminum Angle Adj.  | Tubular without Footplate (Open)<br>Tubular with Plastic Footplate<br>Aluminum Angle Adjustable<br>Aluminum Angle Adjustable with Riser<br>High Mount Aluminum Angle Adjustable  | Aluminum Angle Adjustable with Riser<br>High Mount Aluminum Angle Adjustable   | Composite<br>Aluminum Angle Adjustable<br>Aluminum Footplate  |  |

|                         | Swing Away Extensions (Short, Med, Long)<br>Front Mount Extension | Angle Adj. Flip-Under<br>High Mount Angle Adj. Flip-Under | Angle Adjustable Flip Under<br>High Mount Angle Adjustable Flip Under | Angle Adjustable Flip Under<br>High Mount Angle Adjustable Flip Under | Footplate flip-up                   |
|-------------------------|---|---|---|---|-------------------------------------|
| Seating and positioning | Removable Aluminum Seat Pan                                       | Solid Seat pan  | Solid Seat pan  | Depth Adjustable Seat Pan   | Solid Seat/Back                     |
|                         | Seat Cushions   | Standard Seat Sling                                       | Standard Seat Sling   | Standard Seat Sling   | Jay Cushions                        |
|                         | Backrest  | Seat Cushions   | Seat Cushions   | Seat Cushions   | Jay Back                            |
|                         | Lumbar pads   | Backrests   | Backrests   | Backrest  |                                     |
|                         | Shoulder guides   | Lumbar pads   | Lumbar pads   | Lumbar pads   |                                     |
|                         | Headrest  | Shoulder guides   | Shoulder guides   | Shoulder guides   |                                     |
|                         | Chest supports  | Headrests   | Headrests   | Headrests   |                                     |
|                         | Supports (Chest and Trunk)  | Chest supports  | Chest supports  | Chest supports  |                                     |
|                         | Laterals  | Supports (Chest and Trunk)                                | Supports (Chest and Trunk)  | Supports (Chest and Trunk)  |                                     |
|                         | Positioning belts   | Laterals  | Laterals  | Laterals  | Toe Loop                            |
| Calf straps             | Pelvic Positioning belts  | Pelvic Positioning belts                                  | Pelvic Positioning belts  | Positioning belts   |                                     |
| Heel loops              | Calf straps   | Calf straps   | Calf straps   | Leg Strap   |                                     |
|                         |   |   |   |   | Heel loops                          |
| <b>Accessories</b>      | <b>Ki Mobility Spark</b>  | <b>Ki Mobility Rogue XP</b>                               | <b>Ki Mobility Little Wave XP</b>                                     | <b>Ki Mobility Little Wave Cliik</b>                                  | <b>Zippie GS</b>                    |
| Sideguards              | Composite Side guards (adult and pediatric)                       | Composite Side guards (adult and pediatric)               | Composite Side guards (adult and pediatric)                           | Composite Side guards (adult and pediatric)                           | Composite Side guards (Std and Low) |
| Backpack/Pouch          | Yes   | Yes   | Yes   | Yes   | Yes                                 |
| Spoke Guards            | Yes   | Yes   | Yes   | Yes   | Yes                                 |
| Cane/Crutch Holder      | Yes   | Yes   | Yes   | Yes   | No                                  |
| ELR Gel Pads            | Yes   | No  | No  | No  | No                                  |
| Impact guards           | Yes   | Yes   | Yes   | Yes   | Yes                                 |
| Canopy                  | Yes   | No  | No  | Yes   | Yes                                 |
| Tool Kit                | Yes   | Yes   | Yes   | Yes   | Yes                                 |
| One-Arm Drive           | Yes   | Yes   | No  | Yes   | Yes                                 |

components, wheels and accessories. The seat depth adjustment paradigms of both devices are similar, moving the backrest relative to the front frame. Both the Rogue XP and the Zippie GS utilizes discrete bolts through the backrest into the side frames. The center of gravity is adjustable on both products, with the Rogue XP utilizing clamp on design, while the Zippie GS utilizes discrete bolt positions through side frames. The Ki Mobility Rogue XP uses a nonfolding welded rear frame to provide rigidity to the backrest. The Zippie GS utilizes a dual seat rail system to provide two attachment points for each back cane to provide rigidity. Footrests are separate from side frames. The Zippie GS offers both folding and nonfolding frames, while the Rogue XP only offers a nonfolding frame with integrated footrest tubes. Additionally, the Zippie GS offers a reversible frame, putting the large wheels at the front of the chair and the casters at the rear, while the Rogue XP only offers the conventional orientation with the large wheels in the rear. Different seat heights can be achieved on both products by interchanging wheels and casters, as well as by adjusting the height of the rear wheels on its support, or the casters within the caster forks. The backrest angle of both products is adjustable by use of an array of holes to set discrete seat to backrest angles. The backrests of both products fold down for stowage. The backrests of both products are either fixed height single tubes or a set of telescoping tubes to achieve the backrest heights desired.

The Zippie GS provides a folding mechanism to fold the chair for stowage, while the Rogue XP does not fold laterally. However, the Rogue XP aluminum frame does not present a significant change to the safety or effectiveness of the wheelchair function and has been qualified through testing per the applicable standards. The Rogue XP components and accessories do not pose new risks, being as safe and effective as the predicate device. The Rogue XP is substantially equivalent to the predicate device in intended use, design, materials, and operating principles with no new issues of safety or effectiveness.

The Ki Mobility Little Wave XP manual wheelchair, in comparison to predicate device, shares intended use, similarity of configuration of components, wheels and accessories. The seat depth adjustment paradigms of both devices are similar, moving the backrest relative to the front frame. Both the Little Wave XP and the Zippie GS utilizes discrete bolts through the backrest into the side frames. The center of gravity is adjustable on both products, with both the Little Wave XP and Zippie GS utilizing discrete bolt positions through the tower clamps into the side frames. The Ki Mobility Little Wave XP uses a non-folding welded rear frame to provide rigidity to the backrest. The Zippie GS utilizes a dual seat rail system to provide two attachment points for each back cane to provide rigidity. Footrests are separate from side frames.

The Zippie GS offers both folding and non-folding frames, while the Little Wave XP only offers a non-folding frame with integrated footrest tubes. Additionally, the Zippie GS offers a reversible frame, putting the large wheels at the front of the chair and the casters at the rear, while the Little Wave XP only offers the conventional orientation with the large wheels in the rear. Different seat heights can be achieved on both products by interchanging wheels and casters, as well as by adjusting the height of the rear wheels on its support, or the casters within the caster forks. The backrest angle of both products is adjustable by use of an array of holes to set discrete seat-to-backrest angles. The backrests of both products fold down for stowage. The backrests of both products are either fixed height single tubes or a set of telescoping tubes to achieve the backrest heights desired. The Zippie GS provides a folding mechanism to fold the chair for stowage, while the Little Wave XP does not fold laterally. However, the Little Wave XP aluminum frame does not present a significant change to the safety or effectiveness of the wheelchair function and has been qualified through testing per the applicable standards. The Little Wave XP components and accessories do not pose new risks, being as safe and effective as the predicate device. The Little Wave XP is substantially equivalent to the predicate device in intended use, design, materials, and operating principles with no new issues of safety or effectiveness.

The Ki Mobility Spark manual wheelchair, in comparison to predicate device, shares intended use, similarity of configuration of components, wheels and accessories. The Zippie GS is available with either a foldable or non-foldable frame. The Ki Mobility Spark is only available as a foldable option. Both the Spark and Zippie GS fold by use of an x-brace that attaches to the frame to become rigid, and also have discrete holes that allow for the width of the chair to grow. Additionally, the Zippie GS offers a reversible frame, putting the large wheels at the front of the chair and the casters at the rear, while the Spark only offers the conventional orientation with the large wheels in the rear. The seat depth adjustment paradigms of both devices are similar, moving the backrest relative to the front frame. Both the Spark and Zippie GS utilize discrete through-bolts to adjust the position of the backrest. Different seat heights can be achieved on both products by interchanging wheels and casters, as well as by adjusting the height of the rear wheels on its support, or the casters within the caster forks. The backrest angle of both products is adjustable by use of an array of holes to set discrete seat-to-backrest angles. The backrests of both products fold down for storage. The backrests of both products are either fixed height single tubes or a set of telescoping tubes to achieve the backrest heights desired. The Spark components and accessories do not pose new risks, being as safe and effective as the predicate device. The Spark is substantially equivalent to the predicate device in intended use, design, materials and operating principles with no new issues of safety or effectiveness.

## Non-Clinical and/or Clinical Tests Summary & Conclusions [21 CFR 807.92\(b\)](#)

The Little Wave Klik , Rogue XP, Little Wave XP, and Spark have been tested to meet recognized consensus standards including:  
ANSI/RESNA WC-4:2017 Section 19: Wheelchairs used as seats in motor vehicles  
ISO-7176-1:2014 Determination of static stability  
ISO-7176-3:2012 Determination of Effectiveness of Brakes  
ISO 7176-5:2008 Determination of dimensions, mass, and maneuvering space  
ISO 7176-7:1998 Measurement of seating and wheel dimensions  
ISO 7176-8:2014 Requirements and test methods for static, impact and fatigue strengths

ISO 7176-11:2012 Test Dummies

ISO 7176-13:1989 Determination of coefficient of friction of test surfaces

ISO 7176-15:1996 Requirements for information disclosure documentation and labeling

ISO 7176-16:2012 Resistance to ignition of postural support devices

ISO 7176-19:2022 Wheeled mobility devices for use as seats in motor vehicles

ISO 7176-22:2014 Set-up procedures

Design testing of Little Wave Clik, Rogue XP, Little Wave XP and Spark met or passed the recognized test standard requirements for manual wheelchairs, and which would apply to predicate devices.

Not Applicable

The Little Wave Clik, Rogue XP, Little Wave XP and Spark manual wheelchairs have the same intended use and similar technological characteristics as the predicate devices. The non-clinical testing to recognized standards exhibits that the device will perform as intended and risk analysis has documented risk reduction and identified requirements for labeling for safe and effective use of the device. The Little Wave Clik is substantially equivalent to the predicate devices as shown in the product design comparison.

The conclusion from testing and comparison to predicate devices demonstrates that the Little Wave Clik, Rogue XP, Little Wave XP and Spark are as safe, as effective, and performs as well as the legally marketed devices identified as predicate.